

Remarks/Arguments

This Amendment is being filed in response to the Office action dated March 31, 2004. The undersigned thanks the Examiner for the personal interview granted on June 25, 2004. The Interview Summary Record presents an accurate summary of the interview. Claims 29 and 51 have been amended to include the limitations of Claims 30-32 and to limit the drying gas to nitrogen. Claims 43-50 have been canceled to simplify the issues. The current invention is based upon the unexpected discovery that using a drying gas possessing the claimed range of moisture achieved reproducible, high quality product.

Claims 29-31, 34-37, 40-41, and 47-50 have been rejected as being anticipated by WO 97/39747. WO 97/39747 is directed to a process of coating paracetamol granules to improve the taste of the resulting medicament. The process prepares a slurry of the granules and a coating solution and dries the slurry. The resulting product is then suitable for preparing tablets. The reference is not related to preparing a powder suitable for inhalation (e.g., possessing an aerodynamic diameter of less than 5 microns) by spray drying a liquid feed, or solution. The rejection is clearly moot in light of the amendments to the claims.

Claims 29-37 and 40-51 are rejected as being anticipated by Edwards et al. (USP 5,985,309). Edwards clearly does not teach the specific selection of a nitrogen drying gas having a dew point between about 0 and -40°C. As such, the claims, as amended, are not anticipated by the reference. While the relative humidity is not explicitly described in his reference, it is in the related Mintzes reference. The drying gases actually employed by Edwards possess a much higher dew point than those claimed. Furthermore, while Edwards does teach that varying the inlet temperature and drying gas flow rate can be altered to modify the aerodynamic properties (see Column 27), the dew point of the drying gas is not discussed.

Claims 29-30 and 32-51 are rejected as being anticipated by Jeffrey Mintzes's thesis. As above with Edwards, Mintzes clearly does not teach the specific selection of a nitrogen gas having a dew point between about 0 and -40°C. As such, the claims, as amended, are not anticipated by the reference. Indeed, the drying gases actually

employed by Mintzes (compressed air with a relative humidity between 1-5%) possess a much higher dew point (about 12-40°C) than those claimed herein.

The Examiner has asserted throughout the rejection that the dew point of the drying gas is inherent to the process. The dew point of the drying gas is inherent to the drying gas. However, as exemplified by Mintzes, not all drying gases fall within the scope of the claims. Certainly, the compressed air employed by Edwards and Mintzes do not possess the dew point of Claim 29, as amended, and Claim 31, as previously added. These references do not teach that the quality and reproducibility of the process can be improved by the use of this specific drying gas. The references do not anticipate the claims or make the claimed invention obvious. Withdrawal of the rejections is requested.

Claims 38-39 and 52 are rejected as being obvious over Edwards et al. by itself in view of WO 01/238921. Edwards et al. is relied upon for the reasons stated earlier in the office action. As such, the arguments above are equally applicable in this rejection. The '921 publication is relied upon to show that the use of certain controlling means in a spray drying process is known. Therefore, it is clear that the publication does not teach that which Edwards lacks, as set forth above. Withdrawal of the rejection is requested.

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 251-3509.

Respectfully submitted,

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